510(k) Summary

K073367

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421

Contact Person:

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DEC 27 2007

Prepared:

November 29, 2007

Device Name:

HemosIL Fibrinogen-C

Regulatory Information:

KQJ	System, Fibrinogen Determination	
864.7340	Fibrinogen Determination System	Class II

Predicate Device:

K931721 HemosIL Fibrinogen-C

Device Intended Use:

HemosIL Fibrinogen-C is intended for the quantitative determination of fibrinogen, based on the Clauss method, in human citrated plasma on IL Coagulation Systems.

Device Description:

The Fibrinogen-C kit uses an excess of thrombin to convert fibrinogen to fibrin in diluted plasma. At high thrombin and low fibrinogen concentration, the rate of reaction is a function of the fibrinogen concentration.

Reason for Submission:

The HemosIL Fibrinogen-C test parameters on the ACL TOP are being modified as follows:

- Separate low-end and high-end reflex test parameters are being added to expand the linearity claims on the ACL TOP from the current labeled 80-700 mg/dL to 35-1000 mg/dL.
- The calibration levels are now prepared by aspirating the calibrator directly from the calibrator vial (direct dilution instead of serial dilution).
- The robustness of the assay is increased by optimizing the incubation time and math model.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

The performance of the optimized test parameters for HemosIL Fibrinogen-C on the ACL TOP is substantially equivalent to the performance of the current legally marketed test parameters.

- There are no changes in the reagent's intended use, formulation or operating principle and no changes to the instrument system software, intended use, operating principle or labeled performance claims with this submission.

510(k) Summary (Cont.)

Summary of Performance Data:

Limitations

Current Parameters	Modified Parameters
No Interference	
• Heparin Up to 1 U/mL	• Heparin Up to 1 U/mL
• Hemoglobin Up to 375 mg/dL	• Hemoglobin Up to 375 mg/dL
• Triglycerides Up to 890 mg/dL	• Triglycerides Up to 750 mg/dL
• Bilirubin Up to 21 mg/dL	• Bilirubin Up to 21 mg/dL
• Fibrinogen Degradation Products Up to 100 µg/mL	• Fibrinogen Degradation Products: New testing showed interference from FDP. Therefore, the insert will indicate that Fibrinogen-C assay results on the ACL TOP may be affected by degradation products (fibrin or fibrinogen) in the plasma assayed. This statement is consistent with the language already in use for the other ACL instrument platforms. An associated literature reference regarding FDP interference will be added.

Precision

Current Parameters			Modified Parameters		
Control Level	**Mean**	**Within Run CV**	**Control Level**	**Mean**	**Within Run CV**
Normal	365 mg/dL	7.9%	Normal	303 mg/dL	4.5%
Low Fibrinogen	93 mg/dL	7.7%	Low Fibrinogen	107 mg/dL	5.1%

Linearity

Current Parameters	Modified Parameters
80 – 700 mg/dL	35 – 1000 mg/dL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 27 2007

Instrumentation Laboratory Co.
C/O Carol Marble
113 Hartwell Avenue
Lexington, Massachusetts 02421

Re: k073367
Trade/Device Name: Hemosil Fibrinogen-C
Regulation Number: 21 CFR 864.7340
Regulation Name: Fibrinogen Determination System
Regulatory Class: Class II
Product Code: KQJ
Dated: November 29, 2007
Received: November 30, 2007

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

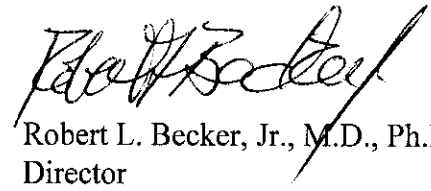
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K073367

Device Name: HemosIL Fibrinogen-C

Indications for Use:

HemosIL Fibrinogen-C is intended for the quantitative determination of fibrinogen, based on the Clauss method, in human citrated plasma on IL Coagulation Systems.

For *in vitro* diagnostic use.

Prescription Use √	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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